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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,496	03/24/2004	Anuschirvan Peyman	446.016-DIV	5709

7590 05/05/2005

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,496	PEYMAN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004 (Pre. Amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Applicant's preliminary amendment of 3-24-04 is acknowledged and entered.

Claims 9 and 10 have been cancelled.

Pending claims 1-8 have been amended.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 1 recites the term "residue" (e.g., "divalent residue") has indefinite metes and bounds because said term suggests an incomplete or impartial structure.

b. In claim 1, the definition of X includes the limitation of "*(amino-(C_1-C_6)-alkyl-NH-, hydroxyl-(C_1-C_6)-alkyl-O-, hydroxyl-(C_1-C_6)-alkyl-S-, and –NH-C(O)-R^6)*" which has indefinite metes and bounds because it is not clear if X is each of those units or a combination of some (or all) of those units.

c. The last limitation of claim 1 has the purine ring replaced by a ring of "*3-deazapurine*", "*7-deazapurine*", or "*7-deaza-8-azapurine*". Said limitation is indefinite

because it is unclear how such a ring is connected to the ring containing Z. Also, it is unclear if variables X, Y and G would be on such a ring, and at the same position.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the make and use of compounds of formula I (with a purine), does not reasonably provide enablement for those of formula I having "*3-deazapurine*", "*7-deazapurine*", or "*7-deaza-8-azapurine*" in the place of the purine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: Claim 1 recites a compound of formula I comprising of three rings, namely, *tetrahydronaphthiridine, cyclohexane or piperidine,* and *purine.* However, the last limitation of claim 1 basically states that the purine can be replaced by a ring of "*3-deazapurine*", "*7-deazapurine*", or "*7-deaza-8-azapurine*". Thus, the scope of claim 1 covers more than just compounds of formula I as drawn. Claims 2-8 depend on claim 1, and thus, have a scope beyond that of formula I with purine as one of the rings.

The amount of direction or guidance presented: The specification only shows the structure of "*3-deazapurine*", "*7-deazapurine*", and "*7-deaza-8-azapurine*". It does not reveal how or where one can obtain starting materials for such a ring. The generic process only describes the starting materials and reaction steps for making a compound of formula I having purine as one of the rings (or a purine compound). As for activity on vitronectin receptor, only purine compounds were tested. Even though purine differs from "*3-deazapurine*", "*7-deazapurine*", and "*7-deaza-8-azapurine*" in the number of ring nitrogen atoms, and/or location, such a difference is a significant structural difference. Thus, the activity of a purine compound cannot be extrapolated to that of a "*3-deazapurine*", "*7-deazapurine*", or "*7-deaza-8-azapurine*" compound. Therefore, the specification does not provide sufficient guidance to make and use compounds other than purine compounds of formula I.

The state of the prior art: As evident by the teaching of **Gilligan et. al.** (US 6,365,589 B1), there is no equivalent teaching for purine and a ring such as: "*3-deazapurine*", "*7-deazapurine*", or "*7-deaza-8-azapurine*". Therefore, there is no guidance for the skilled chemist and/or clinician to make and use compounds other than purine compounds.

The relative skill of those in the art: Even with the advanced training, the skilled chemist and/or clinician would have to engage in undue experimentation to establish data that would adequately support the preparation and use of compounds of formula I with a ring of "*3-deazapurine*", "*7-deazapurine*", or "*7-deaza-8-azapurine*". Such a task would require a tremendous amount of effort, time and resources.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The pharmaceutical art has been known for its unpredictability due to various conflicting pathways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the specification only shows the preparation and biological activity for purine compounds. However, said guidance does not adequately enable the skilled chemist to make compounds of formula I having a different ring since different starting materials and reaction conditions would be required. Also, biological activity for purine compounds does not sufficiently enable the skilled clinician to extrapolate said activity to compounds of a different ring. Thus, with such a limited teaching, the skilled chemist and/or clinician would have to carry out undue experimentation to make and use compounds other than purine compounds of formula I.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,743,800 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed formula overlaps in scope with the formula of US'800 when the disclosed formula has the following substituents:

i. Variable G has the same scope as the one claimed herein.

ii. Variable A has the same scope as the one claimed herein.

iii. Variable B has the same scope as the one claimed herein.

iv. Variables X, Y and Z have the same scope as those claimed herein.

v. Variables R^1-$R^{8'}$ have the same scope as those claimed herein.

The claims of US'800 differ from the instant claims by not reciting the limitation in which the purine ring can be replaed by a ring of "*3-deazapurine*", "*7-deazapurine*", or "*7-*

deaza-8-azapurine". However, it would have been within the level of a skilled chemist to recognize that the purine compounds of US'800 is a subgenus of the one claimed herein. Therefore, it would have been obvious for the skilled chemist to make and use the compounds claimed herein in view of those recited in US'800.

Specification

4. The disclosure is objected to because of the following informalities: Formula III(a) represents two different ring structures.

Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tamthom N. Truong
Examiner
Art Unit 1624

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4-29-05

JAMES O. WILSON
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